

K965086

M. SAFE MEDICAL DEVICES ACT OF 1990 STATEMENT OF SAFETY  
AND EFFECTIVENESS.

"510(k) Summary"

FEB 14 1997

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Contact person: Shaun Sweeney  
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Trade Name : "Cygnus Electrosurgical Tip Protector"  
Common Name: Electrosurgical, Cautery Tip Cleaner  
Classification Name: Electrosurgical Cutting and  
Coagulation Device and Accessories  
(per 21 CFR section 878.4400).

Predicate device:  
Manufacturer  
Devon Industries, CA

Product - Devon Cautery Tip Polisher,  
510(k) Number - K803055

General and Plastic Surgery Device Panel  
Classification - Class II  
Regulatory Citation - 21 CFR ch 1 (4-1-95)

M.1 Product Description

The body of the device is constructed of a polyurethane ester foam. A grit sheet is laminated to the top surface of the foam, and a pressure sensitive adhesive and release liner laminated to the base of the pad. An X-Ray detectable rod is placed between the pressure sensitive adhesive and the foam. The device is available in three sizes. Each pad is individually wrapped and sterilized for use. Sterilization will be by Gamma Ray or ETO and will be conducted and certified by a contract sterilization firm.

M.2 Intended Use of the Device

The primary purpose of the device is to provide a convenient and effective surface for cleaning the tips of electrosurgical cutting and coagulation instruments. The design of the pad is such that the device may be used during surgery and in conjunction with the electrosurgical instrument.

### M.3 Instructions for Use

1. Peel open sterile pouch and remove device.
2. Remove pressure sensitive adhesive from base of pad.
3. Affix the polishing pad to a drape, mayo stand or the most convenient surface area.
4. Stroke electrosurgical blade across the abrasive surface to clean.
5. After use, dispose of pad in a Biohazards container.

### M.4 Technological Characteristics

The technological characteristics of the Cygnus Electrosurgical Tip Cleaner are identical to the predicate devices listed as well as a number of other manufacturers producing this type of product. The self-adhering pad design makes the device convenient and flexible to use. As an abrasive surface, the #60 Aluminum Oxide Impregnated Vinyl Grit Sheet has been in use for over fifteen years and has proven to be effective.

M.5 The "510(k) Substantial Equivalence" Decision-Making Process (detailed) from ODE Guidance Memorandum #86-3 was followed.

A. These products have the same intended use (namely to be used as an abrasive cleaning pad) as the predicate devices. They also have the same intended use as similar products currently cleared for marketing by the 510(k) process.

B. The composition and technological characteristics for the new Cygnus device are the same as those for the predicate devices.

C. Descriptive performance information provided shows that the materials of which the Cygnus product is made, is nearly identical to those of similar products currently on the market.

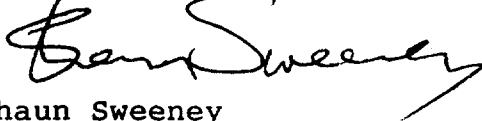
D. Sufficiently precise specifications for the materials of which Cygnus products are constructed have been supplied. These specifications are summarized including comparison with comparative materials.

E. Characteristics of the material used in construction was compared to that of Sybron Medical Products (now marketed by ConMed, Devon Industries and C.R. Bard.

F. Thus, we believe we have supplied sufficient data to show that the CYGNUS products are substantially equivalent to the originally classified device under (CFR 778.4400) and to devices currently on the market, cleared by the 510(k) process.

Having followed the "510(k) Substantial Equivalence" Decision-Making process we feel we have supplied sufficient data to show that the Cygnus Device is substantially equivalent to the originally classified device under (CFR 778.440) and to predicate devices currently being marketed. Your prompt attention to this premarket notification--510(k) will be sincerely appreciated. If there are questions or clarification needed, please call me at 201-827-9333.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Shaun Sweeney", written over a horizontal line.

Shaun Sweeney  
Regulatory Affairs Manager